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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/191,199	11/12/1998	PENG CHO TANG	238/130	8364

7590

04/04/2002

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/04/2002

90

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/191,199

Applicant(s)
TANG et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 22, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-16, 18-37, 41, 44, 45, and 47 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-16, 18-37, 41, 44, 45, and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 29
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Claims 1-9, 11-16, 18-37, 41, 44, 45 and 47 are pending in the application.

This action is in response to applicants' amendment dated January 22, 2002. Claims 42, 43 and 46 have been canceled, claims 1, 4, 13 and 41 have been amended and claim 47 is newly added.

Response to Arguments

Applicants' arguments filed January 22, 2002 have been fully considered with the following effect:

1. The applicants' amendments are sufficient to overcome the improper Markush rejection of claims 42 and 43 in the last office action which is hereby **withdrawn**.
2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 19-37 and 46, the applicants' amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that the basis of the lack of enablement is the recitation of the term preventing and that the deletion of claim 46 renders this rejection moot. The applicants' also stated that "pending claims 19-37 do not recite this term". It is noted that claims 19-37 do not recite the term preventing, however, the basis of the 35 U.S.C. § 112, first paragraph rejection is the enablement of all of the diseases and/or disorders embraced by the claim language, i.e. the method for the modulation of the catalytic activity of a protein tyrosine kinase, the method of treating a protein tyrosine kinase related disorder, etc. There were no arguments presented with respect to this rejection.

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Claims 19-37 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

3. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1-9, 11-16, 19-37 and 41-46, the applicants' amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that "the moiety trihalomethane-carbonyl" has been deleted from the definition of R⁴, R⁵, R⁶, R⁷, R⁸, R⁹ and R¹⁰", however, "trihalomethane-carbonyl" is still present in the definition of R⁴, R⁵ and R⁶ in claim 16.

Claim 16 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a), b), c), d), e), f), g), h), j), k), l), m), n), o), p), q), r), s), t), u), v), w), x), y), z), aa), ab), ac), ad), ae), af), ag), ah), ai), aj), ak), al), am), an), ao), ap), aq), ar), as), at), au), av), aw), ax), ay), az) and ba) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled i)

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of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- i) The applicants' stated that "these terms are clearly defined in the specification", however, "in order to expedite prosecution, the applicants have responded by amending the claims to recite these moieties". However, there is no amendment to claim 5, where one of the substituents for R⁷, R⁸, R⁹ and R¹⁰, is defined as such in the specification that they include variables which are not defined within the claim, i.e. N-amido.

Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejections of claims 41-45 over Buzzetti et al., WO 96/16964 of the last office action, which are hereby **withdrawn**.

6. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1-9, 11-16, 18-37 and 41-46 over Tang et al., U.S. Patent No. 6,147,106 of the last office action, applicants' arguments have been fully considered but are not found persuasive. While evidence of common ownership may now be enough to disqualify commonly assigned art under 103 based on 102(e) as well as 102(f) or (g) in view of the passage of the American Inventors Protection Act, there must

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be provided a clear statement by applicants, attorney or agent of record that instant application and Tang et al., U.S. 6,147,106 **at the time the instant invention was made were commonly owned**. See 1241 OG 96, December 26, 2000.

Claims 1-9, 11-16, 18-37, 41, 44, 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al., U.S. Patent No. 6,147,106. For reasons of record and stated above.

In view of the amendment dated January 22, 2002, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-9, 11-16, 19-37, 41, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed January 22, 2002, included the moiety "five or six membered heterocyclic ring containing at least one nitrogen" in the definition of R¹², R¹³ and R¹⁴, which is not described in the specification with respect to the

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formula. There is no definition in the specification for "heterocyclic". It is believed that the applicants' intended heteroalicyclic.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-9, 11-16, 19-37, 41, 44, 45 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-9, 11-16, 19-37, 41, 44 and 45 are vague and indefinite in that it is not known what is meant by the moiety $R^{12}R^{13}NC(=N)-$ in the definition of Z, R^1 , R^2 , R^4 , R^5 , R^6 , R^7 , R^8 , R^9 and R^{10} , where the $(=N)$ atom is not valence satisfied. It is not known what else is bonded to the N atom.
- b) Claims 1-9, 11-16, 19-37, 41, 44 and 45 are vague and indefinite in that it is not known what is meant by the moiety $-R^{12}NC(=N)NR^{13}R^{14}$ in the definition of R^4 , R^5 , R^6 , R^7 , R^8 , R^9 and R^{10} , where the $(=N)$ atom is not valence satisfied. It is not known what else is bonded to the N atom.
- c) Claims 1-9, 11-16, 19-37, 41, 44 and 45 are vague and indefinite in that it is not known what is meant by the moiety $-NR^{12}C(=O)R^{13}R^{14}$ in the definition of R^4 , R^5 , R^6 , R^7 , R^8 , R^9 and R^{10} , where the carbon atom contains five bonds.

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- d) Claim 1-9, 11-16, 19-37, 41, 44 and 45 are vague and indefinite in that it is not known what is meant by "and" in the phrase and combined, **and** a five or six membered heterocyclic ring containing at least one nitrogen.
- e) Claim 5 recites the limitation "N-amido" in the definition of R^7 , R^8 , R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim.
- f) Claim 16 recites the limitation "trihalomethane-carbonyl and an aryl ring or a heteroaryl ring formed by the combination of R^4 and R^5 " in the definition of R^4 , R^5 and R^6 . There is insufficient antecedent basis for this limitation in the claim.
- g) Claim 41 recites the limitation " $-NR^{12}C(=O)NR^{13}R^{14}$ " in the definition of R^7 , R^8 , R^9 and R^{10} . There is insufficient antecedent basis for this limitation in the claim.
- h) Claims 41, 44 and 45 are vague and indefinite in that it is not known what is meant by the "and" which appears before trihalomethanesulfonyl in the definition of R^1 , indicating the end of the claim which is not so.
- i) Claims 41, 44 and 45 are vague and indefinite in that it is not known what is meant by the "and" which appears before $R^{12}R^{13}NC(=N)-$ in the definition of R^3 , indicating the end of the claim which is not so.
- j) Claims 41, 44 and 45 are vague and indefinite in that it is not known what is meant by the "and" which appears after the definition of R^3 , indicating the end of the claim which is not so.

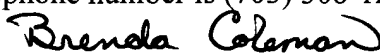
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- k) Claims 41, 44 and 45 are vague and indefinite in that it is not known what is meant by the moiety $-S(=O)_2R$ which appears twice in the definition of R^4 , R^5 and R^6 .
- l) Claim 41 recites the limitation "heteroalicyclic" in the definition of R^{12} , R^{13} and R^{14} . There is insufficient antecedent basis for this limitation in the claim.
- m) Claim 47 is vague and indefinite in that it is not known what is meant by the species in line 17 on page 11, i.e. 3-[4-(4-)-1-methylpyrrol-2-methylidenyl]-5-aza-2-indoline.
- n) Claim 47 is vague and indefinite in that it is not known what is meant by the second occurrence of the species 3-[2-[1-methyl-5-(trifluoromethyl)pyrrol-3-yl]thien-5-methylidenyl]-4-aza-2-indolinone in lines 24-25 on page 15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
Primary Examiner AU 1624
April 2, 2002